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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/687,816

10/20/2003

Eduard N. Lerner

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07/21/2008

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/21/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/687,816	<b>Applicant(s)</b> LERNER, EDUARD N.	
	<b>Examiner</b> CHRISTOPHER D. KOHARSKI	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,4 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4 and 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/3/2003, 3/10/2005</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election without traverse of species A: Figures 2A-2B in the reply filed on 3/25/2008 is acknowledged.

### ***Response to Amendment***

Examiner acknowledges the reply filed 07/16/2008 in which claims 3-4 and 7-12 are pending for examination.

### ***Specification***

The disclosure is objected to because of the following informalities: The priority paragraph needs to be updated to reflect the current disposition of application present in the file history.

Appropriate correction is required.

### ***Drawings***

The drawings are objected to because the element 11 (See Figure 2A) is disclosed as having two different descriptors (i.e. an interior chamber AND an electrode space). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate

changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### ***Information Disclosure Statement***

The information disclosure statements (IDS) that were submitted on 10/03/2003 and 03/10/2005 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

#### ***Specification***

The disclosure is objected to because of the following informalities: It is the Examiner's position that Applicant has invoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner requires the Applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Please note that the MPEP clearly states, "Even if the disclosure implicitly sets forth the structure, materials, or acts corresponding to the means-(or step-) plus-function claim element in compliance with 35 U.S.C. 112, first and second paragraphs, the PTO may still require

the applicant to amend the specification pursuant to 37 CFR 1.75(d) and MPEP 608.01(o)...". (Also see **MPEP 2181** (Rev. 1, Feb.2000))

Appropriate correction is required.

### ***Claim Objections***

Claims 3 and 4 are objected to because of the following informalities: It is the Examiner's position that Applicant has evoked sixth paragraph, means-plus-function language to define Applicant's invention. Therefore the Examiner has objected to the claims for the reasons set forth above in the objection to the specification.

Appropriate correction is required.

Claims 3, 4, 11, 12 are objected to because of the following informalities: Regarding claims 3 and 4, the claims lacks a punctuation marker at the end. Regarding claim 11, the claim terms "means is provided by" should be revised. Regarding claim 12, Applicant appears to incorporate a method step into an apparatus claim. For the purposes of examination, the Examiner will consider the claim limitation as a functional limitation and the drug delivery part is configured to be shaped for expansion in the epidural space. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 7-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Feiring (USPN5,236,413). Feiring discloses a method and apparatus for inducing the permeation of medication into internal tissue.

Regarding claims 3, 7-10 and 12, Feiring discloses an apparatus (Figure 1) capable of enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, comprising: an agent drug delivery device (Figures 3-3a, 14) implantable via catheter (10) to the epidural space of the mammal, a drug reservoir (inside space of 14) with impermeable parts (wall 14) and permeable parts (pores 30), a donor iontophoresis electrode (28) also implantable to the epidural space of the mammal, a receptor iontophoresis (13) electrode that is constructed and capable of being arranged to be positioned at a determined internal or external position of the mammal's body (Figure 4) but in complementary energy gradient positioning to the first electrode, means for providing a potential gradient (44) so that delivery of the biologically active agent is delivered in a direction from said first electrode means directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering said biologically active agent to the spinal structures and/or to the brain of said mammal (Figures 1-4, cols 1-2).

***Claim Rejections - 35 USC § 102***

Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Briskin et al. (USPN5,846,218). Briskin et al. discloses balloon catheter having ultrasonically driven interface surfaces and methods for their use.

Regarding claim 4, Brisken et al. discloses an apparatus (Figure 1) capable of enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, comprising: an agent drug delivery device (60) implantable via catheter (12) to the epidural space of the mammal, a phonophoresis device implantable (120,122) to the epidural space of the mammal, means for providing a potential gradient (14) so that delivery of the biologically active agent (col 3, ln 3-20) is accomplished in a direction from said phonophoresis device directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby delivering said biologically active agent to the spinal structures and/or to the brain of said mammal (Figures 1-14, cols 1-2).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 11 is rejected under 35 U.S.C 103(a) as being unpatentable over Feiring (USPN5,236,413) in view of Rosenthal et al. (USPN6,524,274). Feiring meets the claim limitations as described above except for the swelling drug reservoir.

However, Rosenthal et al. teaches triggered release hydrogel delivery system.

Regarding claim 11, Rosenthal et al. teaches a catheter (51) with an expandable balloon assembly (54, 55) on the distal end thereof, in which a pH swellable (col 3, ln 35-60) hydrogel layer is present as a release substrate for therapeutic agents (Figures 1-7c, cols 1-2).

At the time of the invention, it would have been obvious to use the balloon assembly of Rosenthal et al. with the system of Feiring in order to have a sustained release substrate for therapeutic agents providing a controller release time frame for treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Rosenthal et al. (cols 1-2).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/16/2008

/Christopher D Koharski/  
Examiner, Art Unit 3763

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763